Dated: July 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16617 Filed 7–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3248]

Fosun Pharma USA Inc., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 28, 2024.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 073462 ..	Tolmetin Sodium capsule, Equivalent to (EQ) 400 milligrams (mg) base.	Fosun Pharma USA Inc., 104 Carnegie Center, Suite 204, Princeton, NJ 08540.
ANDA 073588 ..	Tolmetin Sodium tablet, EQ 200 mg base	Do.
ANDA 074002 ..	Tolmetin Sodium tablet, EQ 600 mg base	Do.
ANDA 075631 ..	Ketorolac Tromethamine injectable, 15 mg/milliliters (mL) and 30 mg/mL.	Baxter Healthcare Corp., One Baxter Parkway, Deerfield, IL 60015.
ANDA 076427 ..	Milrinone Lactate injectable, EQ 1 mg base/mL	Do.
ANDA 076791 ..	Haloperidol Lactate injectable, EQ 5 mg base/mL	Do.
ANDA 076828 ..	Haloperidol Lactate injectable, EQ 5 mg base/mL	Do.
ANDA 077040 ..	Citalopram Hydrobromide tablet, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base.	Fosun Pharma USA Inc.
ANDA 077947 ..	Fluconazole injectable, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL).	Baxter Healthcare Corp.
ANDA 078197 ..	Granisetron Hydrochloride (HCl) injectable, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL).	Do.
ANDA 079045 ..	Bicalutamide tablet, 50 mg	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 085787 ..	Trifluoperazine HCl concentrate, EQ 10 mg base/mL	Fosun Pharma USA Inc.
ANDA 086808 ..	Cyproheptadine HCl tablet, 4 mg	Do.
ANDA 087774 ..	Phenylbutazone capsule, 100 mg	Do.
ANDA 088602 ..	Pseudoephedrine HCl; Triprolidine HCl tablet, 60 mg; 2.5.mg	Do.
ANDA 090367 ..	Levofloxacin tablet, 250 mg, 500 mg, 750 mg	Celltrion USA, Inc., U.S. Agent for Celltrion, Inc., One Evertrust Plaza, Suite 1207, Jersey City, NJ 07302.
ANDA 091049 ..	Ceftriaxone Sodium injectable, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, EQ 2 g base/vial.	EAS Consulting Group, LLC, U.S. Agent for Astral SteriTech Pvt. Ltd., 1700 Diagonal Rd., Suite 750, Alexandria, VA 22314.
ANDA 091436 ..	Levofloxacin injectable, EQ 500 mg/20 mL (EQ 25 mg/mL)	Baxter Healthcare Corp.
ANDA 207032 ..	Melphalan HCl injectable, EQ 50 mg base/vial	USWM, LLC, 4441 Springdale Rd., Louisville, KY 40241.
ANDA 207101 ..	Sumatriptan Succinate injectable, EQ 6 mg base/0.5 mL (EQ 12 mg base/mL).	Baxter Healthcare Corp.
ANDA 211959 ..	Clobazam tablet, 10 mg and 20 mg	Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.
ANDA 212053 ..	Chlorzoxazone tablet, 375 mg and 750 mg	AptaPharma Inc., 1533 Union Ave., Pennsauken, NJ 08110.
ANDA 215065 ..	Methocarbamol solution, 1 g/10 mL (100 mg/mL)	Baxter Healthcare Corp.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of August 28, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on August 28, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16627 Filed 7–26–24; 8:45 am]

BILLING CODE 4164–01–P